DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-010

Pharmco Puerto Rico, Inc (d/b/a GlaxoSmithKline)
Attention: Margaret M. Kreider, Ph.D.
Director, U.S. Regulatory Affairs
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Kreider:

Please refer to your supplemental new drug application dated March 2, 2004, received March 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandia® (rosiglitazone maleate) Tablets.

We acknowledge receipt of your submissions dated November 10, and 22, 2004, and May 9, 2005.

Your submission of November 10, 2004, constituted a complete response to our September 3, 2004, action letter.

This supplemental new drug application provides for a Patient Information Leaflet (PIL) for the drug product, Avandia® (rosiglitazone maleate) tablets.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the attached labeling (text for the patient information leaflet) submitted on May 9, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement 21-071/S-010**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (patient information leaflet)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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